

CLAIMS

1. An oral formulation for gastrointestinal drug delivery which comprises an adhesion site-controlling layer for attaching the formulation to the selected site in the digestive tract, a drug-carrying layer for containing a drug and an adhesive and a protecting layer for protecting the drug in the drug-carrying layer, wherein the drug-carrying layer exists between the protecting layer and the adhesion site-controlling layer, and the adhesion site-controlling layer may attach to the protecting layer.

2. The oral formulation for gastrointestinal drug delivery according to claim 1 wherein each of the adhesion site-controlling layer, the drug-carrying layer and the protecting layer is in the form of film, and said three layers are laminated.

3. The oral formulation for gastrointestinal drug delivery according to claim 2 wherein each of the thickness of the adhesion site-controlling layer, the drug-carrying layer and the protecting layer is from 20 to 100  $\mu\text{m}$ .

4. The oral formulation for gastrointestinal drug delivery according to claim 1 wherein the protecting layer is in the hemispherical form, and the drug-carrying layer exists in the inner space of the protecting layer in said hemispherical form, and wherein the adhesion site-controlling layer covers the opening part of the protecting layer in said hemispherical form.

5. The oral formulation for gastrointestinal drug delivery according to claim 4 wherein the inside depth of the hemisphere is from 50 to 500  $\mu\text{m}$ , the inside diameter of the opening part of the hemisphere is from 20 to 800  $\mu\text{m}$ , and each of the thickness of the protecting layer and the adhesion site-controlling layer is from 20 to 100  $\mu\text{m}$ .
6. The oral formulation for gastrointestinal drug delivery according to claim 1 wherein the drug-carrying layer is a porous sheet substrate soaked with a drug, or a sheet or a film of a gel or a wax which contains a drug.
7. The oral formulation for gastrointestinal drug delivery according to claim 1 wherein the drug-carrying layer further contains one or more ingredients selected from the group consisting of absorption promoters, protease inhibitors and transporter inhibitors.
8. The oral formulation for gastrointestinal drug delivery according to claim 1 wherein the protecting layer is a film or a capsule made of a water-insoluble polymer or a wax.
9. The oral formulation for gastrointestinal drug delivery according to claim 1 wherein the adhesion site-controlling layer is a film made of an enteric polymer.
10. The oral formulation for gastrointestinal drug delivery according to claim 1 wherein the drug is a physiologically active protein or peptide.
11. The oral formulation for gastrointestinal drug delivery according to claim 1 wherein the drug is G-CSF,

interferon or indinavir.

*Suly*  
*A1*  
12. An oral capsule formulation which is prepared by filling the formulation according to any one of claims 1 to 11 in a capsule.

13. The oral capsule formulation according to claim 12 which is an enteric capsule.

*add A2*

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*B3*